Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparison study of the therapeutic effect of "honey plus coffee" and inhaled Fluticason/Salmetrol on the chronic bronchiolitis in the chemical injured patients following exposure to sulfur mustard

Protocol summary

Summary

The aim of this study is to investigate the efficacy of different interventions and to compare their effects on improving the respiratory function in the patients with sulfur mustard gas (SM) induced chronic bronchitis or bronchiolitis. About 75 chemical injured patients (CIPs) symptomatic with: cough, dyspnea and night awakening will be randomly and double blindly assigned to three study groups. For every participant a special solution (syrup) is produced, which every 1000 cc of it contains: 500 grams of honey and 70 grams coffee, for the first group (the proper amount for every one week's use), but for the other two groups, it is made of liquid glucose (as uniformity). These participants are told to drink 50 cc of the prescribed solution every 8 hours (for 12 weeks). In addition inhalant sprays are prescribed for them to use three times a day (for 12 weeks). The inhalant spray contains "Normal Saline" (as uniformity) for the first group, "Fluticason 500 micrograms daily / Salmetrol 100 micrograms daily" for the second group, and "Salbutamol 800 micrograms daily / Beclomethasone 1000 micrograms daily " for the third group. Study main outcomes are assessment the cough, dyspnea and night awakening, air trapping in HRCT, increased residual volume in PFT or Spirometry. All the participants will be evaluated before the treatment and at the end of the 2nd, 4th, 8th and 12th weeks. The results will be compared between the study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104294737N4**
Registration date: **2011-05-09, 1390/02/19**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2011-05-09, 1390/02/19

Registrant information

Name

Mohammad Ali Raeessi

Name of organization / entity

Baqiyatallah University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 21 8803 0514

Email address

raeessi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Dr. Mohammad Ali Raeessi + Baqiyatallah University of Medical Sciences

Expected recruitment start date

2010-01-01, 1388/10/11

Expected recruitment end date

2012-12-30, 1391/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison study of the therapeutic effect of "honey plus coffee" and inhaled Fluticason/Salmetrol on the chronic bronchiolitis in the chemical injured patients following exposure to sulfur mustard

Public title
A comparison study of the therapeutic effect of "honey plus coffee" and inhaled Fluticason/Salmetrol on the chronic bronchiolitis in the chemical injured patients following exposure to sulfur mustard
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Chemical injured patients (CIPs) symptomatic with: cough, dyspnea, night awakening. Having significant air trapping in High resolution computed tomography (HRCT) and a marked increase of residual volume in pulmonary function tests (PFT). Exclusion criteria: Other potential causes of chronic cough and lung disease including cigarette smoking.
Age
From **21 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee in Medical Sciences Research, Deputy of Research and Technology, Baqiyatallah Univer
Street address
Sheikhbahaee St., Mollasadra Ave
City
Tehran
Postal code
14359
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
2684

Health conditions studied

1

Description of health condition studied
Chronic bronchiolitis
ICD-10 code
J44.8
ICD-10 code description
Other specified chronic obstructive pulmonary disease

Primary outcomes

1

Description
Cough
Timepoint
On admission and at the end of week 2,4, 8 and12 of the treatment
Method of measurement
Measurement of severity of cough: normal (0), low (+), moderate (++), and severe (+++)

Secondary outcomes

1

Description
Dyspenea
Timepoint
On admission and at the end of week 2,4, 8 and 12 of the treatment
Method of measurement
Measurement of severity: normal (0), low (+), moderate (++), and severe (+++)

Intervention groups

1

Description
First intervention group:Spray of Normal saline + A syrup like solution of 500 gr Honey with 70 gr coffee for every one week. (Duration of intervention is 12 weeks)
Category
Treatment - Drugs

2

Description
Second intervention group:Spray of Fluticason 500 microgr / Salmetrol 100 microgr / daily + A syrup like solution of liquid Glucose. (Duration of intervention is 12 weeks)
Category
Treatment - Drugs

3

Description
Third intervention group: Spray of Salbutamol inhaler

800 microgr daily+ Spray of Beclomethason 1000 microgr daily + A syrup like solution of liquid Glucose. (Duration of intervention is 12 weeks)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah UniversityHospital of Medical Sciences (and the Hospital)

Full name of responsible person

Dr. Mohammad Ali Raeessi

Street address

Mollasadra Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dr. Mohammad Ali Raeessi + Baqiyatallah University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Raeessi

Street address

No117, Molasadra residental complex, Kharazmi st., Mollasadra Ave.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Dr. Mohammad Ali Raeessi + Baqiyatallah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Raeessi

Position

Assistant professor

Other areas of specialty/work

Street address

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty